K121296

510(k) Summary of Safety and Effectiveness

JAN 2 2013

Identification of manufacturer

Company:	Philips Medical Systems Nederland B.V.
Address:	Veenpluis 4-6, 5684-PC, Best, The Netherlands
Registration number:	3003768277

Identification of U.S. designated agent

Company:	Philips Medical Systems
Address:	22100 Bothell Everett Highway Bothell, WA 98021-8431, U.S.A.
Registration number:	1217116

Identification of official correspondent

Name:	Frans Jacobs
Position:	Regulatory Affairs Manager
Telephone:	+31-40-27-99709
Date prepared:	February 3, 2012

Device identification

Trade name:	Interventional Workspot
Device name:	Interventional Workspot Release 1
Regulation description:	Picture archiving and communications system
Regulation number:	21CFR 892.2050
Class:	II
Product code:	90LLZ

Legally marketed devices

Trade names:	Fresco
Manufacturer:	Philips
510(k) numbers:	K031836 – Aug 14, 2003
Trade names:	Allura 3D-RA
Manufacturer:	Philips
510(k) numbers:	K040254 - Feb 19, 2004
Trade names:	Allura 3D-CA
Manufacturer:	Philips
510(k) numbers:	K042334 – Sep 27, 2004
Trade names:	Xper CT
Manufacturer:	Philips
510(k) numbers:	K060749 – Apr 4, 2006

Trade names:	HeartNavigator Release 1
Manufacturer:	Philips
510(k) numbers:	K111245 - Jul 29, 20

Device description

The Interventional Workspot software medical device is a software platform for hosting the aforementioned currently marketed and predicate software medical devices. It provides the same functionalities (for example, import, export, and data handling) that are required by the aforementioned currently marketed and predicate software medical devices to support the physician with performing interventional procedures.

***Indications* for Use:**

Medical purpose / Intended Use:

Interventional Workspot has the following medical purpose:

- import, export, and store digital clinical images.
- manage the patient information associated with those images.

Patient population:

Not applicable because **Interventional Workspot** is only a hosting platform.

Operator profile:

The operator of **Interventional Workspot** has basic understanding of the operating principle of medical computer software.

Technological characteristics

Interventional Workspot software is executed on a PC based hardware platform

Summary of testing

The Interventional Workspot software medical device complies with international recognized standards as detailed in this premarket submission. Non-clinical verification and validation tests were performed with regards to the requirement specifications and risk management results, specifically including software verification, validation and DICOM conformance testing. The results of these tests demonstrate that **Interventional Workspot** met the acceptance criteria.

Conclusion:

The Interventional Workspot software medical device is substantially equivalent to the currently marketed and predicate Philips Fresco, Allura 3D-RA, Allura 3D-CA, Xper CT, and HeartNavigator software medical devices based on the same indications for use, intended use and software requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 2, 2013

Philips Medical Systems Nederland B.V.
c/o Frans Jacobs
Regulatory Affairs Manager
Veenpluis 4-6
BEST, 5684 PC
THE NETHERLANDS

Re: K121296
Trade/Device Name: Philips Interventional Workspot
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 13, 2012
Received: December 26, 2012

Dear Mr. Jacobs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris -
S

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K121296**

Device Name: **Interventional Workspot**

Indications for Use:

The indications for use statement for the proposed Interventional Workspot software medical device, as presented in the IFU, are as follows:

1.1 Device Description

The interventional workspot is a software platform to host Interventional Tools. It provides common functionalities (e.g. import / export and data handling functions) that are required by the Interventional Tools to support the physician with performing the interventional procedure.

1.2 Medical Purpose

The Interventional Workspot has the following medical purpose:

- import, export, and store digital clinical images.
- manage the patient information associated with those images.

1.3 Patient Population

Not applicable because Interventional Workspot is only a hosting platform.

1.4 Intended Operator Profile

The operator of Interventional Workspot has basic understanding of the operating principle of medical computer software.

1.5 Clinical Environment

The software can be used in the control room and in the exam room of an interventional suite and/or operating room.

Prescription Use ___x____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Janine M. Morris -S
2013.01.02 16:10:12 -05'00'

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health